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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,849	07/22/2005	Werner Wessling	R00957US (#90568)	1323

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EXAMINER	
PALENIK, JEFFREY T	
ART UNIT	**PAPER NUMBER**
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,849	WESSLING, WERNER	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21-33* is/are pending in the application.

4a) Of the above claim(s) *9-16 and 22-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,17-19 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *14 Dec 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 29 November 2007 in response to the Requirement for Restriction (filed 26 October 2007), have been fully considered but they are not persuasive.

Applicant's election with traverse of Group I, claims 1-8, 17-19 and 21, is acknowledged. The traversal is on the belief that "Nayak (U.S. Patent 5,989,535) fails to teach a film-shaped administration form" and further "fails to teach "cannabis extract" or "cannabis oil" as set forth in present independent claim 1".

Regarding the "film-shaped" requirement for the composition, Applicant does not set forth any special definition for this term. Section [000033] of Applicant's disclosure provides an open-ended list of examples for the term "film-shaped". Column 2, lines 1-6 teach that the composition of Nayak et al. is formed into an oil-in-water emulsion, latex or suspension, the broadest reasonable interpretation of which is a substance that may be spread over a given part of the body to form a film. Example 8 teaches a bioadhesive **film forming** burn treatment. The broadest reasonable interpretation of this Example embodies a lip treatment to guard against sunburn. Example 13 embodies a lip treatment (i.e. chapstick).

Regarding the "cannabis extract" and "cannabis oil" requirements of the administration form, Applicant does not sufficiently define either the extract or oil compositions within the claims or the disclosure nor the means either's acquisition. The broadest reasonable interpretation of either of these terms, absent any sufficient

definition, is that obtaining any material from cannabis or any mixtures of such ingredients could be considered either "cannabis extract" or "cannabis oil" (see IPER). Furthermore, among the drugs taught by Nayak et al. as one capable of being delivered by the invention is the anti-emetic dronabinol. Dronabinol, marketed under the brand name Marinol® is prepared by dissolving pharmaceutical grade Δ^9-tetrahydrocannabinol, the main extract from cannabis, in sesame oil (col. 5, lines 2-8 of U.S. Patent 6,509,005).

Therefore, Applicant's argument is not found persuasive because the burden of examination is based upon the lack of a unifying special technical feature between the presented Groups I-VI. Per PCT Rule 13.1, the international application shall relate to a group of inventions so linked as to form a single general inventive concept or a "unity of invention" (see MPEP 1850). Per PCT Rule 13.2, said "unity of invention" is fulfilled by defining a special technical feature that is shared amidst the claimed inventions. Per MPEP 1850, since at least one of the independent claims does not avoid the prior art then the question whether there is still an inventive link between all of the claims remains.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9-16 and 22-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (lack of unity) requirement between the product and methods of manufacturing.

Claim 20 was previously cancelled.

The remaining claims 1-8, 17-19 and 21 are presented and represent all claims under consideration.

Priority

This application is the National Stage filing of International Patent Application No. PCT/EP03/04807, filed 8 May 2003, and German Foreign Application 102 26 494.5, filed 14 June 2002. Examiner finds that Applicant's filing meets the priority requirements for the International Application, but not the Foreign Application.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Acknowledgment is made of Applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in Germany on 14 June 2002. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter.

As such it is determined that the earliest effective U.S. filing date to be 8 May 2003.

Information Disclosure Statement

An Information Disclosure Statements filed 14 December 2004 is acknowledged and has been reviewed.

Specification

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, *e.g.*, "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

Applicant is also reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Complete revision of the content of the abstract is required on a separate sheet.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 6, 18 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The terms "cannabis extract" and "cannabis oil" in claim 1 lack clarity. The terms are vague and indefinite because neither the claim nor the specification define the composition of said extract or oil, or the means through which either is to be acquired.

The term "and/or" in claim 3 is a relative term which renders the claim indefinite. The term "and/or" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The scope of the invention is unclear as to which properties of the selected polymer(s) are to be considered.

Claim 6 recites the limitation "the layer thickness" in the first and second lines of the claim. There is insufficient antecedent basis for this limitation in the claim.

Regarding the "layer" limitation recited in claims 6 and 21, it is not clear to which layer of the administration form Applicant is referring. Paragraphs [000034] and [000035] of Applicant's specification use the term "layer" in reference to both the overall composition as well as the individual units composing the administration form. Therefore, the broadest reasonable interpretation of both claims is that *any one* of the layers must meet the respective thickness range. These claims are prosecuted herein under this interpretation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-8, 17, 19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Yates (U.S. Patent 6,319,510).

Claim 1 recites a film-shaped, mucoadhesive administration form comprising either a cannabis extract or cannabis oil. Claim 2 further limits the composition such it further comprises a polymer matrix which acts as a reservoir to the active cannabis agent. Claim 3 further limits the polymer(s) that may form the matrix to those that are water-soluble and/or expandable under aqueous conditions. In addition to providing a list of potential polymers, claim 3 also further limits the administration form to containing 5% to 95% by weight of the polymer(s). Claim 17 further limits the previous polymer percent range to 15% to 75% by weight. Claim 5 further limits the administration form of claim 1 by adding a flavoring, aromatic or odorous substance to the composition. Claim 19 further limits claim 5 by providing a list of possible compounds. Claims 6 and 21 recite a limitation to the dosage form of claim 1 wherein the thickness of "the layer" per claim 6 ranges from 0.1 mm to 2.0 mm and per claim 21 ranges from 0.05 mm to 0.5 mm. Claim 7 further limits the dosage form of claim 1 by including at least one type of inactive ingredient (i.e. sweetener or filler) in the composition. Claim 8 recites that the administration form of claim 1 has a multilayer structure wherein at least one of the layers contains the active agent.

Such compositions are taught to be made by Yates. Claims 1 and 10 teach a multi-layered, "gum pad" composition for use in the mouth of a person wherein a second

adjacent layer contains the medication, is capable of being liquefied by saliva, and is made to form a reservoir (i.e. contained between two layers). Claim 16 teaches dronabinol as the active agent used in the gum pad. The reservoir layer is taught to contain the medication which is mixed or compounded with: (1) water soluble particulate material or (2) water soluble support matrix (col. 7, line 66 to col. 8, line 1). Yates further provides a listing of different materials useable in either of the two aforementioned matrices such as collagen, chitosan, cellulose derivatives, etc. (col. 8, lines 2-54). Regarding the composition of said matrix, Yates teaches that a hydrogel matrix may be comprised of approximately 20 wt% to 85 wt% of hydrophilic polymer (col. 10, lines 13-15). Flavoring agents, such as mint, which provides the scent for menthol (instant claim 19) and sweeteners are taught (col. 9, lines 24-27). Different individual layers of the gum pad composition are taught that have thicknesses within the recited ranges. The high flux, semi-permeable membrane materials can have a thickness of 1-10 mils (col. 13, lines 25-26), which converts to a range of 0.025 mm to 0.25 mm (per www.onlineconversion.com). Additionally, the thickness of the backing layer is taught to range from 0.3 mm to 3.0 mm (converted from cm; col. 7, lines 5-7).

Therefore each and every one of the limitations is met by the reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 17-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yates (U.S. Patent 6,319,510).

The instant claims are directed to a film-shaped, mucoadhesive administration form comprising a cannabis extract or oil embedded within a polymeric matrix reservoir, as described above. Claim 4 further limits the dosage form by reciting an amount of active cannabis agent present ranging from 0.5 to 50 wt%. Claim 18 further limits claim 4 by reciting a narrower active agent range of 1 to 30 wt%. As described before, such compositions are taught to be made by Yates. He further teaches that the concentration of the medication mixed into the reservoir should range from about 0.005% to about 25% (by weight of the total dispersion) and preferably ranging from 0.1% to about 10%. Were the a dry weight of the medication to be considered for formulation into the matrix the range to be considered is from about 0.005% to about 95% and preferably from 0.1% to about 80% (col. 7, lines 51-56). Furthermore, Yates teaches a thickness for the semi-porous and backing layers of the overall gum pad composition, which, when considered

individually, fall within Applicant's recited thickness for "the layer". Considered together, the thickness of the two layers can be as thin as about 0.325 mm.

This does not take into account the thickness of the medicated reservoir, for which Yates only provides volumetric ranges on the order of about 0.2 mL to about 4.0 mL (col. 7, lines 46-49). In addition to Yates not providing a specific thickness for the reservoir, he also does not teach the specific percent weight range for the active medication mixed into the polymeric reservoir matrix. However, since parameters such as the amount of active cannabis agent of the composition and the thickness of the reservoir layer are adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to optimize the polymeric reservoir matrix, both in thickness and in percent weight contained of the active agent, in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicant's invention.

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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